U.S.S.N. 09/585,911
GREEN *et al.*
AMENDMENT AND RESPONSE

AMENDMENTS TO THE CLAIMS:

1. (Currently amended) A method of providing anti-infective activity to a medical device, ~~comprising~~ comprising:

a) providing a medical device ~~which~~ that is at least in part within a patient; then

b) delivering an oxidant generating formulation to the medical device, thereby exposing the medical device to an anti-infective oxidant; and

c) transferring the anti-infective oxidant into a wall of the medical device.

2. (Currently amended) The method of ~~claim 1~~ claim 1, wherein the medical device has a lumen, and including exposing a wall defining the lumen to the anti-infective oxidant.

3. (Currently amended) The method of ~~claim 2~~ claim 2, wherein the medical device is a catheter having a shaft defining the lumen and having a balloon with an interior in fluid communication with the lumen of the catheter shaft, and including exposing an inner surface of the balloon to the anti-infective oxidant.

4. (Currently amended) The method of ~~claim 2 including delivering a formulation which generates the oxidant~~ claim 2, wherein the oxidant generating formulation that generates the oxidant is delivered into the lumen of the medical device.

5. (Previously presented) The method of claim 4, including inserting a tubular delivery member, into the lumen of the medical device, the tubular delivery member having a lumen configured to deliver the oxidant generating formulation into the lumen of the medical device.

6. (Currently amended) The method of ~~claim 4~~ claim 4, including, after step (c), removing the oxidant generating formulation from the lumen of the medical device.

7. (Currently amended) The method of ~~claim 4~~ claim 4, including inhibiting expulsion of the oxidant generating formulation from the lumen of the medical device by providing a viscosity increasing hydrogel in the oxidant generating formulation.

8. (Currently amended) The method of ~~claim 4~~ claim 4, wherein the anti-infective oxidant comprises elemental iodine, and including combining a first solution comprising an iodide and a second solution comprising an iodate such that an elemental iodine generating formulation is produced, and delivering the elemental iodine generating formulation to the lumen of the medical device.

9. (Currently amended) The method of ~~claim 4~~ claim 4, wherein the anti-infective oxidant comprises elemental iodine and the oxidant generating formulation comprises an iodide and an oxidoreductase, and including exposing the oxidoreductase to a substrate to generate protons or an iodide oxidizing agent, so that the oxidant generating formulation produces elemental iodine.

10. (Currently amended) The method of ~~claim 9~~ claim 9, including exposing the medical device to a body fluid having the substrate to generate protons or an iodide oxidizing agent, so that the oxidant generating formulation produces elemental iodine when contacted with the body fluid.

11. (Currently amended) The method of ~~claim 4~~ claim 4, wherein the anti-infective oxidant comprises elemental iodine and the oxidant generating formulation comprises an iodate, and including exposing the iodate to a reducing agent to generate elemental iodine.

12. (Currently amended) The method of ~~claim 2~~ claim 2, including inserting an oxidant releasing member into the lumen of the medical device.

13. (Currently amended) The method of ~~claim 12~~ claim 12, wherein the oxidant releasing member has an elongated body configured to be slidably inserted into the lumen of the medical device, and further including, before step (b), exposing the oxidant

releasing member to a formulation which generates the oxidant so that the oxidant diffuses into the oxidant releasing member.

14. (Currently amended) The method of ~~claim 13~~ claim 13, wherein the anti-infective oxidant comprises elemental iodine, and including exposing the oxidant releasing member to an elemental iodine generating formulation comprising an iodide, and iodate and a proton source.

15. (Currently amended) The method of ~~claim 14~~ claim 14, including transferring about 2 ppm to about 300 ppm of the oxidant from an exterior surface of the medical device to the patient.

16. (Currently amended) The method of ~~claim 1~~ claim 1, including, after step (c), diffusing the oxidant to an outer surface of the medical device.

17. (Currently amended) The method of ~~claim 1~~ claim 1, wherein the anti-infective oxidant comprises elemental iodine, and including transferring about 2 ppm to about 300 ppm of the elemental iodine from an exterior surface of the medical device to the patient.

18. (Currently amended) The method of ~~claim 1~~ claim 1, including transferring the anti-infective oxidant within about 1 to about 30 minutes.

19. (Currently amended) The method of ~~claim 1~~ claim 1, wherein the anti-infective oxidant is elemental iodine, and including preventing the binding of the elemental iodine within the wall of the medical device.

20. (Currently amended) The method of ~~claim 19~~ claim 19, wherein the binding of the ~~element~~ elemental iodine is prevented by providing a medical device which is free of iodine binding agents.

21. (Currently amended) The method of ~~claim 4~~ claim 4, wherein the formulation includes a binding agent which is bindable to the anti-infective oxidant, and including

binding an amount of the generated anti-infective oxidant to the binding agent to thereby inhibit transfer of the bound anti-infective oxidant into the medical device wall.

22. (Currently amended) The method of ~~claim 21~~ claim 21, wherein the binding agent is selected from the group consisting of silicone oil, mineral oil, cadexomers, and polyvinylpyrrolidone, and including increasing a duration over which at least about 2 ppm of the anti-infective oxidant is transferred into the medical device wall.

23. (Currently amended) The method of ~~claim 21~~ claim 21, wherein the anti-infective oxidant comprises elemental iodine, the binding agent comprises polyvinylpyrrolidone, and the polyvinylpyrrolidone is about 1% to about 10% weight per unit volume of the formulation, and including increasing a duration over which at least about 2 ppm of the elemental iodine is transferred from an exterior surface of the medical device to the patient.

24. (Currently amended) The method of ~~claim 4~~ claim 4, including positioning an insert member into the lumen of the medical device to thereby reduce the amount of formulation delivered into the medical device lumen.

25. (Previously presented) An anti-infective oxidant releasing member, comprising an elongated body configured to be slidably disposed within a lumen of a medical device and an anti-infective oxidant releasably contained within the elongated body.

26. (Currently amended) The anti-infective oxidant releasing member of ~~claim 25~~ claim 25, wherein the elongated body comprises a solid rod.

27. (Currently amended) The anti-infective oxidant releasing member of ~~claim 26~~ claim 26, wherein the solid rod further includes at least one channel on an outer surface of the rod configured to allow fluid flow therein.

28. (Currently amended) The anti-infective oxidant releasing member of ~~claim 25~~ claim 25, wherein an outer diameter of the elongated body is about 90% to about 5% less than an inner diameter of the lumen of the medical device.

29. (Currently amended) The anti-infective oxidant releasing member of ~~claim 25~~ claim 25, wherein an outer diameter of the elongated body is about 20% less than an inner diameter of the lumen of the medical device.

30. (Currently amended) The anti-infective oxidant releasing member of ~~claim 25~~ claim 25, wherein the oxidant comprises elemental iodine.

31. (Currently amended) The anti-infective oxidant releasing member of ~~claim 26~~ claim 26, wherein the elongated body is formed of a polymeric material, and wherein elemental iodine is diffusible within the polymeric elongated body.

32. (Currently amended) A method of providing anti-infective activity to a medical device, ~~comprising~~ comprising:

a) exposing the medical device to a solution [[which]] that produces an anti-infective oxidant by inserting an anti-infective oxidant releasing member into the device; and

b) transferring a sufficient amount of anti-infective oxidant into a wall of the medical device to provide the medical device with anti-infective activity.

33. (Currently amended) The method of ~~claim 32~~ claim 32, wherein the solution is aqueous and the anti-infective oxidant is elemental iodine.

34. (Currently amended) The method of ~~claim 33~~ claim 33, wherein the aqueous solution produces at least about 0.1 ppm of elemental iodine.

35. (Currently amended) The method of ~~claim 33~~ claim 33, including transferring about 2 ppm to about 300 ppm of the elemental iodine from an exterior surface of the medical device to [[the]] a patient.

36. (Currently amended) The method of ~~claim 35~~ claim 35, wherein step (a) further comprises exposing the medical device a single time to the aqueous solution.

37. (Currently amended) The method of ~~claim 36~~ claim 36, wherein the aqueous solution produces about 2 ppm to about 10 ppm of iodine.

38. (Currently amended) The method of ~~claim 33~~ claim 33, including transferring not greater than about 1000 micrograms a day of the elemental iodine from an exterior surface of the medical device to [[the]] a patient.

39. (Currently amended) A method of providing anti-infective activity to a medical device, ~~comprising~~ comprising:

a) exposing an oxidant releasing member to a formulation [[which]] that generates an anti-infective oxidant, ~~so that the anti-infective oxidant~~ that diffuses into the oxidant releasing member; and

b) ~~exposing the medical device to the oxidant releasing member~~ inserting the anti-infective oxidant releasing member into the medical device so that the anti-infective oxidant diffuses from the oxidant releasing member into a wall of the medical device.

40. (New) A method of providing anti-infective activity to a medical device, comprising:

a) inserting an anti-infective oxidant releasing member into the medical device, wherein the member is configured to be adjacent to or in the medical device; and

b) transferring the anti-infective oxidant into a wall of the medical device.

41. (New) The method of claim 40, wherein the medical device is at least in part within a patient.